Supreme Court, U.S.
FILED

(1) 96 761 NOV 14 1996

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No. 96-

IN THE

Supreme Court of the United States

October Term, 1996

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,

Cross-Petitioner,

v.

BRACCO DIAGNOSTICS INC., and BRACCO INTERNATIONAL B.V., ORGANON, INC., MERCK & CO., INC., MSD TECHNOLOGY, L.P., SCHERING CORPORATION, HOFFMAN-LA ROCHE, INC., and SYNTEX (U.S.A.), INC.,

Cross-Respondents,

and

DAVID A. KESSLER, M.D., Commissioner of Food and Drugs, and BRUCE A. LEHMAN, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks

Cross-Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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18 pp

QUESTION PRESENTED

A drug patent may receive only one extension under the Hatch-Waxman Act, 35 U.S.C. § 156. The extension period is required to be calculated by the Patent and Trademark Office from the "original expiration date" of the patent at the time PTO grants an extension. The extension becomes "part of the original patent." The question presented is whether the court of appeals erred in ruling that § 156 permits a patentee who received such an extension of its patent term before the effective date of the Uruguay Round Agreements Act ("URAA") to take a second Hatch-Waxman extension of a new patent expiration date made available under the URAA?

PARTIES AND RULE 29.6 STATEMENT

All parties in the consolidated appeal proceedings before the Federal Circuit are listed in the caption.

Cross-Petitioner Generic Pharmaceutical Industry Association is a New York not-for-profit corporation. It has no parent companies, subsidiaries or affiliates. The following firms are members, associate members and affiliate members of the association: A.L. Pharma Inc., Apothecon, Barr Laboratories, Clonmel Healthcare Ltd., Copley Pharmaceutical, Inc., Creighton Products Corporation, Endo Laboratories L.L.C., ESI Lederle Generics, Geneva Pharmaceuticals, Inc., Global Pharmaceutical Corporation, Zenith Goldline, Hoechst Celanese Corporation, Lemmon Company, Perrigo Company, Rosemont Pharmaceutical Corporation, Hoechst Marion Roussel, Inc., Schein Pharmaceutical, Inc., Warner Chilcott Laboratories, Warrick Pharmaceuticals, ACIC Limited, Agvar Chemicals, Inc., Aesgen, Inc., Darby Group Companies, Inc., GYMA Laboratories of America, HMS Sales & Marketing, Inc., Interchem Corporation, KRKA, Lek USA, Inc., Pharma-Kinetics Laboratories, Phoenix International Life Sciences, PLIVA USA INC., Ranbaxy Pharmaceuticals, Inc., Ren-Pharm International, Ltd., Century Financial Services, Inc., Newport Data Associates, Inc., ScinoPharm International, Ltd., CCL Label, Intercall, Inc., and MIM Promark Holdings.

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CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

In No. 96-575, Bracco Diagnostics Inc. and Bracco International B.V. (collectively, "Bracco") jointly petitioned this Court for a writ of certiorari to review a judgment of the United States Court of Appeals for the Federal Circuit. The Generic Pharmaceutical Industry Association ("GPIA"), one of the respondents in No. 96-575, conditionally cross-petitions for a writ of certiorari to the Federal Circuit to review the same judgment that is the subject of the Bracco petition. If the Court grants the Bracco petition, it should grant GPIA's cross petition as well.[1] The Federal Respondents also filed a conditional cross-petition for a writ of certiorari on November 8, 1996, relating to the same Federal Circuit decision, which was docketed as No. 96-728.

OPINIONS BELOW

The opinion of the Court of Appeals is reported as *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed.Cir. 1996), and is reproduced in the appendix to the Bracco Petition in Docket 96-575 (hereinafter cited as "Pet.App.") at pages 1a-20a. The opinion of the district court, *Merck & Co. v. Kessler*, 903 F.Supp. 964 (E.D. Va. 1995), is reproduced at Pet.App. 23a-28a. The order of the district court on remand, set forth at Pet. App. 29a-34a, is not officially reported.

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[1]Organon Inc. filed a petition similar to Bracco's in No. 96-562. However, as the Federal Respondents' brief in opposition to that petition pointed out, Organon's patent expired on November 6, 1996, depriving that matter of any live controversy. The Organon petition did not suggest any other fact or circumstance that would prevent its case from having become moot at that time.

JURISDICTION

The Court of Appeals entered its judgment on April 4, 1996 (Pet.App. 21a-22a) and denied all petitions for rehearing on July 12, 1996. (Pet.App. 35a-40a). Bracco's Petition for a writ of certiorari was placed on this Court's docket on October 15, 1996. This conditional cross-petition is timely under Supreme Court Rule 12.5. The Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are 35 U.S.C. § 154, derived from the Uruguay Round Agreements Act of 1994, Pub. L. 103-465, 108 Stat. 4809 (1994) ("URAA"), and 35 U.S.C. § 156, derived from the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984)(the "Hatch-Waxman Act"). These provisions are set out in the appendix to the Bracco Petition, Pet.App. 54a-73a.

STATEMENT OF THE CASE

Most of the facts and proceedings in the case are set forth in the Bracco Petition at pp. 2-6, and in the Counterstatement of the Case in GPIA's brief in opposition to the Bracco Petition, filed in No. 96-575 simultaneously herewith. Additional facts relevant to this conditional cross-petition are as follows:

The position of the Federal Respondents in the courts below was that the phrase "original expiration date" as used in the Hatch-Waxman Act, 35 U.S.C. § 156, had a fixed meaning that remained constant throughout the life of the

patents at issue here — namely the date 17 years from issuance of the original patent, regardless of any change in patent term pursuant to the URAA. GPIA's approach to reconciling Hatch-Waxman and the URAA was slightly different: GPIA stressed the fact that the grant of a Hatch-Waxman extension under § 156 is not self-executing. It occurs as a result of a formal application to and action by the Patent and Trademark Office ("PTO") after a precisely spelled out, multi-step process. Under the statutory requirements, this once-per-patent process takes place shortly after approval by the Food and Drug Administration ("FDA") of the drug covered by the patent, so that all concerned will know promptly what the extended patent term is. To compute the statutorily prescribed length of an extension, while taking account of various mandatory constraints — especially the 14-year limit on total exclusive market life after the date of FDA approval — the statute and regulations explicitly require PTO to determine and utilize the "period remaining in the [patent's] term," 35 U.S.C. § 156(c)(3), *i.e.* the "original term," *see* 37 C.F.R. § 1.775(d)(2), or the "original expiration date," *see* 37 C.F.R. §§ 1.775(d)(5)(i), (d)(6)(i)(A), (d)(6)(ii)(A), ***as of the time PTO grants the extension***. Upon grant of the extension, a certificate of extension is issued by PTO and must be "recorded in the official file of the patent and shall be considered as part of the original patent" according to 35 U.S.C. § 156(e)(1).

Thus, GPIA argued, since each of the patents in this case had received its one-time Hatch-Waxman extension from PTO before the effective date of the URAA, when the expiration date of each patent was 17 years from date of issuance of the patent, the Hatch-Waxman extension was explicitly determined with respect to, and inextricably

attached to, the then-existing patent expiration date and became "part of" that "original" patent. GPIA pointed out that there is simply no provision in § 156 — nor, for that matter, in the URAA transition provision, 35 U.S.C. § 154(c)(1) — for a second calculation or issuance of an extension already granted, or for severing the prior extension from "the original patent" and re-attaching it to a newly established patent expiration date.

The difference between the government's position and the GPIA position did not affect any patent at issue in this case. However, as a theoretical matter, a patent issued before the URAA effective date, but as to which no Hatch-Waxman extension was granted until after that date, would receive different treatment under the two approaches. Under the government's approach, such a patent would have its post-URAA extension attached to its permanent "original" 17-year term, while under the GPIA approach, the post-URAA PTO extension process would, following the regular procedures of § 156, compute the extension with respect to the then applicable 20-year term and automatically attach this initial Hatch-Waxman extension to that term.

The Federal Circuit rejected the government's position that "original expiration date" means an immutable point in time, once a patent is granted. However, in considering GPIA's alternative approach, the court read the GPIA position narrowly, focussing solely on GPIA's point that the 14-year limit would have to be recalculated by PTO if the pre-URAA extensions were severed from the already extended 17-year term and re-attached to the newly established 20-year term:

> GPIA argues for denial of pre-URAA restoration extensions precisely because FDA [*sic*[2]] would have to recalculate the allowable number of days to insure that the 14-year restriction is met. We do not agree with appellants that pre-URAA patentees should be denied restoration extensions for this reason. GPIA's interpretation would treat otherwise equal patents unequally depending on when the patentee applies for and the FDA [*sic*[3]] grants an extension. Correction to fit within the 14-year limitation entails only a purely ministerial task, no more taxing than the recalculation of a new date for a patent extended by URAA alone (that is, without a restoration extension).

Pet.App. 16a.[Footnote omitted.[4]]

The court did not address GPIA's points that Hatch-Waxman extensions are not self-executing, that they are required to be performed by PTO at a specific time, that they require a determination of the "original expiration date" as of

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[2] Like Bracco, Bracco Pet. p. 4, the Court apparently confused the roles of FDA and PTO in the Hatch-Waxman process. While the FDA (as designee of the Secretary of Health and Human Services) does have a role in reporting the number of days that a drug has spent in the FDA approval process, and in determining due diligence, *see* 35 U.S.C. § 156(d)(2), the ultimate calculation and grant of an extension is committed to the PTO, see 35 U.S.C § 156(e)(1).

[3]See footnote 2. The fact that this error was made twice has serious implications which are discussed below.

[4]The omitted footnote points out that the district court had failed to perform the "purely ministerial task" of computing and applying the 14-year limit applicable to one of the patents at issue.

that time, and, once granted by PTO, that they become part of the "original" patent, *i.e.* the patent in force at the time of PTO's action under § 156.

However, the court did accept, at least in part, three of GPIA's key points:

1. The district court had rejected GPIA's argument that, as to all patents with pre-URAA Hatch-Waxman extensions, the post-URAA act of attaching a (recalculated) Hatch-Waxman extension to the newly established 20-year term would constitute a prohibited second extension. However, the Federal Circuit accepted in principle the general premise of this point. It ruled that, as to those patents which had begun utilizing their pre-URAA § 156 extensions before the URAA effective date — five of the twelve patents at issue in the case — "a reapplication of the restoration extension would constitute a second extension contrary to the statute." Pet.App. 18a. Of course, the reason for this cross-petition is that the Court of Appeals did not apply the same principle to the other seven patents at issue, all of which also had received pre-URAA first extensions.

2. In rejecting the government's position that "original expiration date" forever refers to the 17-year term of pre-URAA patents, the Federal Circuit concluded "that 'original expiration date' means no more than that the expiration date has not been extended under section 156(e)(1) and, thus, the phrase can identify more than one date." Pet.App. at 15a. The court cited as an example the grant of a new type of non-Hatch-Waxman extension under § 154(b)(2), "which would be added to the term *prior* to the addition of a restoration extension which, under section 156(a), is added to the end of what would otherwise be the patent term." This interpreta-

tion, focussing on the status quo ***at the time of the Hatch-Waxman extension***, coincides exactly with the GPIA interpretation; however, as discussed below, the court failed to follow this interpretation to its logical conclusion.

3. Rejecting the idea that it could avoid the excess extension problem for a Bracco-type patent by splitting the extension between the pre-URAA time already used and the time to be added to the URAA, the Court declined "to rewrite the statute." Pet.App. 19a. But again it provided no reasoned explanation of why its retroactive recalculation and reissuance of the seven re-extended patents was not such a rewriting, since neither statute provided for that process or that result.

REASONS FOR GRANTING THE CROSS-PETITION

GPIA's brief in opposition to Bracco's petition for certiorari in No. 96-575 explains why this case does not meet the standards for this Court's review of the issue raised by Bracco, namely the Federal Circuit's denial of a second extension to patents which had begun to utilize their prior Hatch-Waxman extensions before the effective date of the URAA, and why the circuit court decision on that issue was correct.

However, should this Court decide to grant the Bracco Petition and review the decision below on that issue, the Court should also grant this cross-petition in order to consider the Federal Circuit's error in affirming the judgment of the district court with respect to seven of the patents in the

case.[5] That error was the failure to recognize that severance of any pre-URAA Hatch-Waxman extension from the term that it had become "part of," and its recalculation in respect to, and re-attachment to, the subsequently authorized 20-year term, is equally the granting of a prohibited second Hatch-Waxman extension, accomplished without any of the clearly specified and time-limited administrative actions required by Congress, and without any authority in any provision of the two laws at issue, thus constituting a "rewriting" by the court of those laws.

In addressing this case, the Court of Appeals conceded that it was acting on a matter which Congress had not "expressly" addressed in either Hatch-Waxman or the URAA. Pet.App. 8a. It ultimately stated its goal as adopting an interpretation under which "all provisions of both URAA and Hatch-Waxman can reasonably be given effect." *Id.* at 14a. GPIA respectfully submits that, to achieve that goal, the court should have applied to all patents granted extensions before June 8, 1995, the same logic, and same constraints of Hatch-Waxman, as it applied to the patents which happened to begin using their extensions before that date. The court should have drawn its bright line between patents which *received* their Hatch-Waxman extensions before and those which *received* their extensions after the URAA effective date, rather than between those which *began using* their

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[5]GPIA, as previously indicated, does not consider the Organon petition in No. 96-562 a viable petition since even under the district court's decision, which the Federal Circuit reversed, Organon's patent would now have expired, apparently rendering its claim moot.

extensions before and those which *began using* their extensions after that date.

First, adding pre-URAA Hatch-Waxman extensions onto the end of 20-years-from-date-of-application expiration dates newly granted to patents eligible under the URAA transition clause would fulfill none of the purposes of either law. As the Court of Appeals noted, Pet.App. 7a, the purpose of the URAA was not to extend patents but to conform U.S. patent law to the laws of most other developed nations, which use the 20-years-from-application standard. That goal was met as soon as each patent in force on June 8, 1995, was given the option of applying the 20-year calculation if that would give it a longer life than its pre-existing patent life under the prior law. And no purpose of Hatch-Waxman is served by giving these transitional patents a life longer than the life granted by PTO when their one-time Hatch-Waxman extensions were applied for, calculated, and issued. Those extensions fully provided whatever retroactive or prospective benefit that Congress intended to offer these patentees when, in 1984, it provided for extensions to the 17-year term.

Second, the Court of Appeals decision conflates the mechanism of the URAA transitional provision, which Congress made self-executing so that all existing patents would meet the URAA 20-year standard automatically on the effective date, with the mechanism of Hatch-Waxman, which is not self-executing at all, but requires an elaborate administrative process culminating in PTO's discrete act of granting a § 156 extension. That process takes place only once in time, upon an application by the patentee within 60 days of FDA approval of the patented drug, and explicitly requires the PTO to determine at that time "the period

remaining in the term of [the] patent after [FDA's] approval of the approved product...." *See* §§ 156(d)(1)), 156(c)(3). As the court conceded, neither Hatch-Waxman nor URAA explicitly authorizes or directs any departure from this statutory scheme by PTO, by a court, or by patentee self-certification. The fact that some of PTO's functions may be seen as "ministerial" does not erase the fact that they are Congressionally mandated.

In fact, the court's repeated erroneous reference to FDA (see notes 2 & 3, *supra*) as the source of the calculation and grant of a Hatch-Waxman extension suggests that it may not have sufficiently focussed on the details of the PTO's Hatch-Waxman responsibilities, and thus may not have fully appreciated the non-self-executing nature of this process. On the other hand, the court did recognize, in rejecting the government's "fixed original expiration date" approach, that the § 156 process would now have to take into account the new non-Hatch-Waxman extensions before adding on the Hatch-Waxman time. But that logic suggests that in every case the term extended by PTO under Hatch-Waxman must be the term in existence at the time the one-time statutory Hatch-Waxman process is completed, which for these patents was prior to the URAA effective date, when the only patent term to which the extensions could be added was the 17-year term. If this Court addresses these issues, it should apply that logic.

Third, the Court's complaint that "GPIA's interpretation would treat otherwise equal patents unequally depending on when the patentee applies for and the FDA [*sic*] grants an extension" (Pet.App. 16a) is not persuasive in the context of two statutes rife with arbitrarily drawn bright lines, which

drastically change the outcome for particular patents which may have only a day's difference in their chronology. For example, Hatch-Waxman limits extensions on certain patents to two years and others to five years, depending on whether or not the patent was issued, or other actions occurred, before or after the date of enactment of Hatch-Waxman. *See* § 156(g)(6). And URAA limits transitional treatment to those patents applied for or granted before June 8, 1995. *See* § 154(c)(1). A patent applied for on June 9, 1995, will receive ***only*** the 20-years-from-application term, even if the 17-year-from-issuance term would have been longer. Similarly, a patent which expired on June 7, 1995, the day before URAA took effect, was lost forever, even if 20 years from its date of issue would have been well after June 7, 1995; but a patent which under previous law would have expired on June 9, 1995, will be extended to the 20-year-from-date-of-application expiration date if that date is later than June 9, 1995. Surely GPIA's conclusion, that § 156 defines a Hatch-Waxman extension as of the date it is granted, establishes a bright line that is no more arbitrary, and probably more fair, than the other bright lines found in these statutes.

Fourth, the court correctly concluded that the belated addition of a further extension to the URAA term of a patent in force on June 8, 1995, only because of its previous Hatch-Waxman extension would constitute a prohibited second Hatch-Waxman extension. But if this is so as to those patents, it should also be so as to all patents with pre-URAA § 156 extensions, which pursuant to the statute became an integral "part of" those patents. The fact that they had not begun to utilize the extended portion of those terms should not be determinative, because they eventually receive the full benefit

of the extended 17-year term if that term is better for them than the transitional URAA 20-year term.

In short, contrary to its stated intention, the Court of Appeals did rewrite the statute, and it did so in a manner that unnecessarily conflicts with the law as written. Its ruling means that § 156(e)(1) now reads as follows [the imputed new language is shown in italics]:

> ... If the Commissioner [of Patents] determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension ... a certificate of extension ... for the period prescribed by subsection (c), *except that, if this extension has not yet begun to run, and the patentee wants its extension severed from this patent term and recalculated, and re-granted with respect to some new patent term established by Congress, the requirement of subsection (a)(2) that the patent has never before been extended under this subsection shall not apply, and the 14 year limit which PTO is required to calculate may be calculated by the patentee, and the patentee may self-certify its new patent expiration date without action of PTO, without issuance of the required certificate of extension, and without provision for the required recording of the new date in the official file of the patent.*

Perhaps if Congress had been lobbied by the patentees to adopt such an amendment to Hatch-Waxman, it might have done so, despite what would have been the strong opposition of the generic drug industry, and the patient community. But

there is no need to speculate on what might have been: Congress did not do so, and there is no basis for any court to step in to "rewrite the statute" under these circumstances.

GPIA's common-sense reading of the statutes meets all of the purposes of both laws, without running afoul of the language of either. It should be adopted by this Court, if it decides to review the decision of the Court of Appeals.

CONCLUSION

The Court should grant GPIA's conditional cross-petition for a writ of certiorari to the Federal Circuit in the event that it grants the Bracco Petition in No. 96-575.

Respectfully submitted,

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November 14, 1996

Supreme Court, U.S.
FILED
DEC 9 1996
CLERK

(2) (2)

Nos. 96-728, 96-761

IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1996

DAVID A. KESSLER, M.D ET AL.,
ConditionalCross-Petitioners,

v.

ORGANON, INC., ET AL.,
Respondents.

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION
Conditional Cross-Petitioner,

v.

BRACCO DIGNOSTICS INC., ET AL.,
Respondents.

On Conditional Cross-Petitions for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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QUESTION PRESENTED

In 1984, Congress enacted the Hatch-Waxman Act. One part of this act, codified at 35 U.S.C. § 156, states that any patent covering a drug whose marketing is delayed because of regulatory review by the Food and Drug Administration shall receive patent term restoration to compensate for part of that regulatory delay.

In 1994, in a transitional provision in the Uruguay Round Agreements Act, 35 U.S.C. § 154(c)(1), Congress mandated that the term of any patent in force on June 8, 1995, or resulting from an application filed prior to that date, shall be the greater of 20 years from filing of the patent application or 17 years from the grant of the patent, subject to any terminal disclaimer.

The question presented by the conditional cross-petitioners in this case is whether the Court of Appeals for the Federal Circuit erred when it determined that the patent of a drug whose marketing was delayed due to FDA regulatory

review was entitled to the term of 20 years from filing of the patent application mandated by the URAA together with the patent term restoration period authorized by the Hatch-Waxman Act, subject only to the restrictions on term restoration established by the Hatch-Waxman Act.

LIST OF PARTIES

This Opposition to Petitions for Writ of Certiorari is filed on behalf of Merck & Co., Inc., MSD Technology, L.P. and Schering Corporation. The parent company, non-wholly owned subsidiaries, and affiliates of Merck & Co. that have issued shares to the public are:

Banyu Pharmaceutical Co., Limited
Banyu ASC Co., Ltd.
Nippon Merck Banyu Co.Ltd.
Prodome Quimica e Farmacaeutica Ltda.
Kronans Droghandel AB
Kiineiesto Oy Irmelinpesa
Comnet Corporation

MSD Technology, L.P. is a limited partnership, comprised of four partners, three of which are wholly-owned subsidiaries of Merck & Co., Inc. The fourth partnership interest in MSD Technology, L.P. is held by Abbey National Treasury Services, P.L.C.

The parent company, non-wholly owned subsidiaries, and affiliates of Schering Corporation that have issued shares to the public are: Schering-Plough Corporation.

Other parties to the proceedings in the United States Court of Appeals for the Federal Circuit were: Bracco Diagnostics Inc. and Bracco International B.V.; Hoffmann-La Roche Inc. and Syntex (U.S.A.) Inc.; Organon, Inc.; David A. Kessler, M.D., Commissioner of Food and Drugs; Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks; and the Generic Pharmaceutical Industry Association.

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35 U.S.C. § 156(d)(2)(B) (Supp. 1996) 15

35 U.S.C. § 156(e) (Supp. 1996) 2,11

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FEDERAL REGISTER

60 Fed. Reg. 15748 (Mar. 27, 1995) 16

60 Fed. Reg. 30069 (June 7, 1995) 16

CONGRESSIONAL RECORD

129 Cong. Rec. S.6313 (daily ed. May 19, 1983) 10

Nos. 96-728, 96-761

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1996

DAVID A. KESSLER, M.D., ET AL.,
Conditional Cross-Petitioners,
v.

ORGANON, INC., ET AL.,
Respondents.

GENERIC PHARMACEUTICAL
INDUSTRY ASSOCIATION,
Conditional Cross-Petitioner,
v.

BRACCO DIAGNOSTICS INC., ET AL.,
Respondents.

On Conditional Cross-Petitions for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF OF RESPONDENTS MERCK & CO., INC., MSD TECHNOLOGY, L.P. and SCHERING CORPORATION IN OPPOSITION

STATUTES INVOLVED

The statutory issues raised by the conditional cross-petitioners in 96-728 and 96-761 arise under the Drug, Price Competition, and Patent Term Restoration Act (the "Hatch-Waxman Act"), codified in relevant part at 35 U.S.C. §§ 156 (a) and (e).

STATEMENT OF THE CASE

The relevant facts and the proceedings below are set forth in the brief in opposition of respondents Merck & Co., Inc., MSD Technology, L.P (together "Merck") and Schering Corporation ("Schering") filed in 96-562 and 96-575.

REASONS FOR DENYING THE WRIT

These cross-petitions for writ of certiorari are conditional on the grant of the petitions in 96-562 and 96-575. The reasons for denying the petitions in those two cases are discussed at some length in the brief in opposition of respondents Merck and Schering. *See* Merck/Schering Opp. at 8-15. Additional grounds for denial are presented by the

conditional cross-petitioners themselves in their oppositions to those two petitions. *See* Fed. Opp. at 9-15; GPIA Opp. at 4-6.

To summarize, the petitions in 96-562 and 96-575 should be denied because they do not present issues of general importance and do not concern a conflict with the decisions of this Court or of any court of appeals. At least one of the arguments raised in 96-562 is not properly presented for review. Moreover, the case in 96-562 is moot.

Even if certiorari were granted in 96-562 or 96-575, however, the conditional cross-petitions should be denied. In addition to the fact that the conditional cross-petitioners themselves acknowledge that this case does not present any issue of general importance -- a point highlighted by the decision of the Solicitor General not to seek certiorari in the normal course -- cross-petitioners cannot show a substantial basis for believing that the court below erred in its interpretation of the Hatch-Waxman Act.

The interpretation of the Hatch-Waxman Act adopted by the court below is the only reading faithful to the language, history, and structure of the Hatch-Waxman Act. Federal cross-petitioners are incorrect in their assertion that the court below erred by not deferring to the "Final Determination" of the PTO, which claimed to interpret provisions of the Hatch-Waxman Act, as this is not a case where *Chevron* deference applies. Moreover, the interpretation of the Hatch-Waxman Act urged by federal cross-petitioners cannot be reconciled with the statutory language, history, and structure of the statute. Nor is there any better support in the statute for the different position taken by conditional cross-petitioner Generic Pharmaceutical Industry Association ("GPIA"), which correctly rejects the position taken by the federal cross-petitioner. *See* 96-761 Cross-Pet. at 6-7.

1. To secure review by this Court in the absence of a conflict among circuits,[1/] conditional cross-petitioners must demonstrate both that there is a substantial basis for believing that the court below erred in its construction of the governing statute and that the issue has substantive importance. *See* Sup. Ct. R. 10(c). The cross-petitioners are unable to meet this standard.

As the conditional cross-petitioners forthrightly acknowledge, this case does not present an issue of general importance. Rather, the case concerns only a transitional provision of highly attenuated significance. *See* 96-728 Cross-Pet. at 3; *see also* 96-761 Cross. Pet. at 7. Even that limited significance is being continually eroded by time, as additional patents subject to the transitional rules of 35 U.S.C. § 154(c)(1) expire. For example, as the cross-petitioners

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[1/] Cross-petitioners do not claim that this case presents a circuit split. Moreover, because the determination of issues arising under 35 U.S.C. § 156 are within the exclusive jurisdiction of the Federal Circuit under 28 U.S.C. §1295(a)(1), there could not be a conflict among the circuits on the issues presented here.

pointed out in their briefs in opposition in 96-562 and 96-575, the passage of time has already made the case in 96-562 moot. *See* Fed. Opp. at 9; GPIA Opp. at 2.

2. Nor can the conditional cross-petitioners show a substantial basis for believing that the court below erred in its construction of the governing statute. None of the cross-petitioners challenge the Federal Circuit's holding that all of the patents in issue were in force on June 8, 1995, *see* 35 U.S.C. § 154(c)(1), which is the only issue decided below that required an interpretation of the Uruguay Round Agreements Act ("URAA"). Thus, the only issue of law raised by the cross-petitioners is whether the Federal Circuit correctly interpreted the Hatch-Waxman Act. On that latter point, the holding of the Federal Circuit relies on an interpretation of the Hatch-Waxman Act that, unlike those proposed by the conditional cross-petitioners, conforms with the mandatory language of the statute and is equally supported by the history and structure of the Act.

In the URAA, Congress changed the terms of patents from 17 years from grant of the patent to 20 years from filing of the patent application. Transitional provisions incorporated in the URAA require that the term of patents in force on June 8, 1995, or that result from applications filed before that date "shall be the greater of" 17 years from grant or 20 years from filing. 35 U.S.C. § 154(c)(1). (Emphasis added). The wording of the URAA is unequivocal and mandates a 20-year-from-filing term in all cases where the patent was in force on June 8, 1995, and the 20-year term exceeds the term of 17 years from grant.[2/]

The Hatch-Waxman Act, enacted a decade earlier than the URAA, authorizes patent term restoration as partial compensation for the loss of effective patent life[3/] suffered by products, such as drugs, that are subject to FDA pre-

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2/ As this Court has repeatedly held, Congress's use of the word "shall" establishes an inflexible requirement. *See, e.g., Fogarty* v. *Fantasy, Inc.*, 510 U.S. 524, n.11 (1994).

3/ The term "effective patent life" refers to the period between FDA marketing approval for the product and the expiration of patent protection.

marketing regulatory review.[4/] 35 U.S.C. § 156. Section 156(a) states that eligible patents "shall be extended in accordance with this section from the original expiration date of the patent." (Emphasis added.) The Federal Circuit held that the term "'original expiration date' means no more than that the expiration date has not been extended under section 156(e)(1)." *See* 96-562 Pet. App. at 17a. The Federal Circuit's interpretation of this phrase is based directly on the language Congress added to Section 156(a)(2) when it enacted the URAA and is unambiguously supported by the legislative history of the Hatch-Waxman Act and the structure of 35 U.S.C. § 156.

When the Hatch-Waxman Act added Section 156 to Title 35, the term of patents, including those subject to Hatch-Waxman term restoration, was 17 years from grant. No

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[4/] The Hatch-Waxman patent term restoration periods do not compensate fully for the time lost in regulatory review, but merely "ameliorate the loss incurred when patent terms tick away while the patented product is awaiting [FDA] regulatory approval for marketing." *Unimed, Inc.* v. *Quigg*, 888 F.2d 826, 829, 12 U.S.P.Q.2d (BNA) 1644, 1647 (Fed. Cir. 1989).

extensions of that term were available for any patents other than pharmaceutical patents covering products whose marketing had been delayed by the FDA's regulatory processes. The phrase "original expiration date" in Section 156(a) simply served to distinguish the expiration date of a patent prior to consideration of the Hatch-Waxman Act from the expiration date inclusive of the Hatch-Waxman term restoration period.

This understanding is directly confirmed in a 1982 letter from the congressional draftsman of the phrase, then-Congressman Tom Railsback, to Bruce A. Lehman[5/] explaining why the phrase had been inserted into legislation that later became Section 156(a). *See* 96-562 Pet. App. at 15a-16a. This letter makes it clear that "original expiration date" refers to the date on which the patent would have

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5/ At the time, Congressman Railsback was the ranking minority member of the Subcommittee on Courts, Civil Liberties, and the Administration of Justice, which had substantive jurisdiction of the matter, and Mr. Lehman was counsel to the subcommittee. Mr. Lehman is now Commissioner of Patents and Trademarks and one of the cross-petitioners.

expired if not for the addition of a Hatch-Waxman restoration period.

> The insertion of 'from the original expiration date of the patent' . . . makes specific what was intended, namely, that the maximum extension . . . must be calculated from the original date of the patent. Thus, 2 five-year regulatory review periods for 2 different products under the same patent will result in only one extension from the original patent expiration date.

The single change that the URAA made in the Hatch-Waxman Act provides further direct support for the Federal Circuit's decision. The URAA amended 35 U.S.C. § 156(a)(2) by adding the underscored phrase to provide that a Hatch-Waxman extension may be granted as long as "the term of the patent has never been extended under subsection (e)(1) of this section." This change was needed because other provisions of the URAA for the first time[6/] permitted patent

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[6/] Prior to the enactment of the Hatch-Waxman Act in 1984, Congress added Sections 155 and 155A of the Patent Act, which provide statutory term extensions for a limited number of patents covering the food additive aspartame (Section 155) and the drug forane (Section 155A). *See United Sweetener USA, Inc.* v. *Nutrasweet Co.*, 760 F. Supp. 400, 419 (D. Del. 1991) (aspartame); 129 Cong. Rec. S. 6313 (daily ed. May 19, 1983) (statement of Mr. East) (forane).

term extensions for reasons other than FDA regulatory delay.[7/]

This amendment explicitly demonstrates the Congressional expectation that a patent term enlarged by the URAA could also benefit from Hatch-Waxman restoration under 35 U.S.C. § 156. The Hatch-Waxman restoration period of such a patent would be calculated from its "original expiration date," *i.e.*, the date the patent would expire if it were not extended pursuant to 35 U.S.C. § 156(e)(1). Thus, the language and structure of Section 156(e) as amended by the URAA also compels the Federal Circuit's interpretation of "original expiration date" (*see supra* p. 8) and its conclusion that respondents Merck and Schering are entitled to add Hatch-Waxman term restoration periods to the URAA-mandated 20-years-from-filing terms of their patents in suit,

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7/ The URAA authorized patent term extensions under 35 U.S.C. § 154(b)(1) to compensate for the loss of effective patent life resulting from interference delay and secrecy orders and authorized patent term extension under 35 U.S.C. § 154(b)(2) to compensate for delays due to appellate review of an adverse determination of patentability.

subject only to any applicable restrictions contained within the Hatch-Waxman Act itself.

3. The primary claim of the federal conditional cross-petitioners is that the Federal Circuit should have deferred to the interpretation of the statute by the PTO under *Chevron, U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984). 96-562 Pet. App. at 14a.

This is plainly not a case where *Chevron* deference is appropriate. This case does not involve any issue relating to the PTO's particular expertise in an area in which Congress has granted it discretionary powers.[8/] *Compare Babbitt* v. *Sweet Home Chapter of Communities for a Great Oregon,* 115 S.Ct. 2407, 2418 (1995) (deference granted to agency with "broad discretion" in circumstances requiring "an expertise and attention to detail that exceeds the normal province of

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[8/] This case thus stands in sharp contrast to *Smiley* v. *Citibank (South Dakota) N.A.*, 116 S.Ct. 1730 (1996), for example, which concerned an interpretation of the banking laws by the Comptroller of the Currency, who "is charged with the enforcement of banking laws *to an extent that warrants the invocation of* [deference]." *Smiley,* 116 S.Ct. at 1733 (citations and internal quotation marks omitted) (emphasis added).

Congress"). This case does not involve the PTO's special expertise in scientific matters. Rather, it concerns the interpretation of the Patent Act. The federal judiciary has for two centuries been and remains the final arbiter of the meaning of the patent statue. The Federal Circuit has plainly been correct in repeatedly holding that no deference is due to the PTO's interpretations of the Patent Act. *See, e.g., Hoechst Aktiengesellschaft* v. *Quigg*, 917 F.2d 522, 526 (Fed. Cir. 1990) (no deference granted to PTO interpretation of ambiguous statutory language); *Glaxo Operations U.K., Ltd.* v. *Quigg*, 894 F.2d 392 (Fed. Cir. 1990) (in cases involving dissection of statutory language, courts are equally skilled in making interpretations).[2/]

[2/] It is worth noting that the Solicitor General did not seek a writ of certiorari in either of these cases. This is consistent with the position taken by the Solicitor General in the present case in opposing the petitions for certiorari in 96-562 and 96-575 and in other cases where the Federal Circuit refused to defer to the PTO's interpretation of the Hatch-Waxman Act. *See Ethicon, Inc.* v. *Quigg*, 849 F.2d 1422 (Fed. Cir. 1988) (certiorari not sought).

It is indicative of the PTO's limited role in interpreting the patent statute that Congress has granted the PTO only very limited rulemaking authority. As the Federal Circuit has held, the broadest of the PTO's rulemaking powers, found in 35 U.S.C. § 6(a), authorizes the Commissioner to promulgate regulations only "for the conduct of proceedings in the [PTO]," and does not grant authority to issue substantive rules. *See Ethicon, Inc.* v. *Quigg*, 849 F.2d 1422, 1425 (Fed. Cir. 1988). Accordingly, the PTO's statutory interpretation "cannot possibly have the force and effect of law." *Animal Legal Defense Fund* v. *Quigg*, 932 F.2d 920, 930, U.S.P.Q.2d at 1686 (Fed. Cir. 1991).

The PTO particularly lacks substantive rulemaking power over the Hatch-Waxman Act, for its role in the administration of the statute is purely clerical. The PTO receives applications for patent term restoration under the Hatch-Waxman Act, but is required to notify the FDA immediately. 35 U.S.C. § 156(d)(2)(A). The FDA

determines the period of regulatory delay that occurred and is authorized to hold a hearing and to resolve disputed issues as appropriate. 35 U.S.C. § 156(d)(2)(B). The PTO's role is limited to making certain arithmetic calculations after being informed of the length of the regulatory delay by the FDA.[10/] The calculation of the patent term restoration period is a purely mechanical exercise, involving addition and subtraction but no discretion.

4. In this case, it would be particularly inappropriate for the judiciary to defer to the PTO's interpretation of the Hatch-Waxman Act in light of the PTO's substantive flip-flop on the issue presented in this case. On

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[10/] The PTO calculates the length of the patent term restoration period by adding half the number of days that the patented product or method underwent clinical trials to the number of days the subsequently filed "New Drug Application" was pending before the FDA, subject to two limitations. First, the restoration period cannot exceed five years for patents issued subsequent to the enactment of the Hatch-Waxman Act; patents issued prior to the enactment of the Hatch-Waxman period generally are limited to a two-year extension. 35 U.S.C. § 156(g)(6). *Cf. Hoechst Aktiengesellschaft* v. *Quigg*, 917 F.2d 522 (Fed. Cir. 1990) (patent term restoration not limited by Section 156(g)). Second, the effective patent life cannot exceed 14 years. 35 U.S.C. § 156(c)(3).

March 27, 1995, after extensive consideration, the PTO published a "Proposed Determination" concerning the application of the URAA patent term transitional provision to patents in force on June 8, 1995, that qualified for term restoration under the Hatch-Waxman Act. 60 Fed. Reg. 15748 (Mar. 27, 1995). In this statement, the PTO expressed the view that the terms of such patents should be computed by adding the Hatch-Waxman restoration period to the end of the 20-year URAA term.

On June 7, 1995, the PTO completely reversed the position it had articulated ten weeks earlier and issued a so-called "Final Determination" announcing a revised view that holders of patents in force on June 8, 1995, and subject to Hatch-Waxman patent term restoration, "are entitled" to the longer term of either "(a) 17 years from grant, supplemented by the period of extension [under the Hatch-Waxman Act]," or "(b) 20 years from their relevant filing date," without any Hatch-Waxman restoration period. 60 Fed. Reg. 30069 (June

7, 1995). The PTO cited no new information that justified this about-face. *Id.* The PTO simply changed its mind.

5. Even if the PTO's interpretations of the Hatch-Waxman Act were generally entitled to deference under *Chevron*, the PTO's interpretation of "original expiration date" deserves no such deference because it cannot be reconciled with the language, history, and structure of the statute. The federal conditional cross-petitioners cannot explain away the Railsback letter, so they attempt to dismiss it as "superfluous."[11/] *See* 96-928 Cross. Pet. at 10. Nor can the federal cross-petitioners square the PTO's position with the sole amendment the URAA made to the Hatch-Waxman Act. If "original expiration date" meant the expiration date anticipated on the day the patent was granted, a patent extended under provisions other than 35 U.S.C. § 156(e)(1),

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11/ Recent amendments to the Hatch-Waxman Act, however, do not affect the historical import of the Railsback letter which, as the Federal Circuit recognized, helps explain the meaning of the phrase "from the original expiration date of the patent."

such as Section 154(b) as amended by the URAA, would be barred from also receiving Hatch-Waxman term restoration. Such an outcome is clearly contrary to the language of 35 U.S.C. § 156(a)(2).

Federal conditional cross-petitioners also claim that permitting the addition of Hatch-Waxman restoration periods to the URAA mandated 20-years-from-filing term could result in the violation of 35 U.S.C. § 156(c)(3), which places a 14-year limit on the effective patent life of a patent that has received Hatch-Waxman term restoration. *See* 96-728 Cross-Pet. at 10-11. They disregard the fact that the 14-year rule is one of the limitations on patent term restoration that is directly incorporated in the Hatch-Waxman Act and that the Federal Circuit held to be applicable to patents whose terms are enlarged by the transitional provisions of Section 154(c)(1).[12/] As the Federal Circuit recognized, nothing

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12/ The district court and Federal Circuit both held that the term of Merck's U.S. Patent No. 4,283,408 must be calculated so as not to exceed (continued...)

more than an arithmetical calculation is required to conform with the 14-year rule of section 156(c)(3). *See* 96-562 Pet. App. at 17a-18a.[13/]

6. The wholly distinct interpretation of the Hatch-Waxman Act urged by conditional cross-petitioner GPIA similarly lacks foundation in the statutory language. GPIA concurs with the Federal Circuit's interpretation of "original expiration date", but argues that permitting a Hatch-Waxman restoration period that was granted prior to June 8, 1995, to be added on to a URAA-mandated 20-years-from-application term would constitute a second application of a restoration

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[12/](...continued)
the 14-year limit on effective patent life set forth in 35 U.S.C. 156(c)(3). *See* 96-562 Pet. App. at 18a-19a; 96-575 Pet. App. at 33a.

[13/] Federal conditional cross-petitioners also raise the specter of the "problem of fitting together the different limitations on remedies during successive extensions," and suggest that the only way to address this problem is to prohibit in all cases the addition of a Hatch-Waxman term restoration period to a URAA-mandated 20-year-from-filing term. *See* 96-728 Cross-Pet. at 11, n. 9. Thus far, no reported case presenting such a problem has arisen, supporting the Federal Circuit's conclusions that "this problem is more illusory than real," and that "the majority of patents should not be denied extensions because of a mere possibility that special problems may arise in a few instances." *See* 96-562 Pet. App. at 19a-20a.

period in violation of Section 156(a).[14/] This argument, which was considered and rejected by the Federal Circuit, has no basis in the language of the statute and suffers from the additional flaw that it assumes that the URAA *sub silentio* withdrew previously certified Hatch-Waxman term restoration periods from pharmaceutical patents assigned the 20-years-from-filing term by Section 154(c)(1). If the URAA had been intended to affect patent term restorations in such a manner, Congress would have to have explicitly amended the language of Section 154 or Section 156. *See, e.g., Bristol-Myers Squibb* v. *Royce Laboratories,* 69 F.3d 1130, 1136 (Fed Cir. 1995), *cert. denied.,* 116 S.Ct. 754 (1996) (had Congress intended URAA to change Hatch-Waxman, it would have done so explicitly).

[14/] GPIA appears to call into question the mandatory nature of the transitional provision of the URAA, Section 154(c)(1), by claiming that the statute provides each patent "the option" of applying the 20-year-from-application patent term. 96-761 Cross. Pet. at 9 (emphasis added). As discussed above, Section 154(c)(1) is clearly mandatory. *See supra* p. 7.

CONCLUSION

The conditional cross-petitions in 96-728 and 96-761 for a writ of certiorari should be denied.

Respectfully submitted,

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December 9, 1996